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This report is best read in conjunction with European Union level reports written by the Office of Agricultural Affairs of the U.S. Mission to the European Union in Brussels, BELGIUM, under the "Food and Agricultural Import Regulations and Standards (FAIRS)" category.

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SECTION I. FOOD LAWS

The major Spanish legislation governing food products is the 1974 Food Code (Codigo Alimentario) which has been subsequently amended by a number of decrees, orders, and particularly by specific food product technical-sanitary regulations (Reglamentos Tecnico Sanitarios) as well as by all the European Union's food legislation which has been transposed into Spanish legislation.

SECTION II. LABELING REQUIREMENTS

A. General Requirements

Royal Decree 1334/99 (State Gazette No. 202 of August 24, 1999) is the General Norm on labeling, advertising and presentation of packaged food products. Royal Decree 930/92 (State Gazette No. 187 of August 5) regulates nutritional labeling. These two royal decrees are transpositions into Spanish legislation of EU Directives 79/112 and 90/496 and amendments, respectively. A summary of the General Norm on labeling is provided below.

General Labeling Requirements (Royal Decree 1334/99)

This norm is applicable to food products destined to consumers as well as to HRI establishments.

All labeling information must be at least in the Spanish language. Stickers are allowed.

The following mandatory information must be shown on the food container labels:

- product sales name (1)
- ingredient list
- the quantity of certain ingredients or categories of ingredients
- alcoholic content in beverages with an alcoholic level of over 1.2 percent, volume basis
- net quantity for packaged products
- expiration date marking
- special directions for conservation and utilization
- directions for utilization, where applicable
- company identification: name and address of manufacturer, packer or seller based in the EU.
- lot marking
- country of origin
- the additional indications set in Annex IV when applicable

(1) Product sales name must be that provided by EU laws or in the absence of any EU law by Spanish Standards or other Spanish food laws. In its absence, product sales name must be the customary name in Spain or a description of the food product indicating the true nature of the product. However, when all this would not enable consumers to know the true nature of the foodstuff and to tell it from products

with which they could be confused, the sales name must be accompanied by other descriptive information.

- Product sales name can not be substituted by a brand name or an imaginary name.
- Product sales name (1) should include or should be accompanied by an indication of the physical condition of the product or the specific treatment given (whether it is in powder or dry-freezing form, frozen, concentrate, smoked), if omission of this description may confuse the buyer.
- Any foodstuff which has been treated with ionizing radiation must bear the following indication: "IRRADIADO" or "TRATADO CON RADIACION IONIZANTE".
- When the foodstuff is regulated by specific provisions, quality standards must be indicated.

2) Ingredients: (Sp. INGREDIENTES: ..) list of ingredients in decreasing order, by weight, upon their incorporation into the manufacturing process; except added water if its content does not exceed 5 percent in weight of the finished product. For products to be diluted such as beverage mixes, the list of ingredients should be read in Spanish INGREDIENTES DEL PRODUCTO RECONSTITUIDO:... or INGREDIENTES DEL PRODUCTO YA PREPARADO PARA EL CONSUMO:... and should contain the final product's ingredients in decreasing order.

2.1. Natural and artificial flavors. Natural and artificial flavor(s) must be called "AROMA(S)" or by "AROMA(S) followed by the flavor name or a more specific description. Royal Decree 1477 of November 2, 1990 lists the maximum content allowed in food and beverages of certain aromatizing substances. The Decree also includes lists of plants (or part of the plant) forbidden in the elaboration of natural flavoring; positive and limited lists of artificial substances; positive lists of additives, diluents and carriers authorized in the elaboration of aromas, and positive list of diluents.

2.2 Ingredients belonging to any of the categories listed in Annex I (see page 5 of this report) should only be listed with the category name.

2.3. Food additives: The ingredient list must also include food additives at its end. Food additives which belong to one of the groups listed in the Annex II (see page 6 of this report) must be named with the group's name followed by their specific name or EEC number (E number).

The quantity of an ingredient or category of ingredients, expressed as a percentage at the time of its use, should be indicated either in or next to the product sales name (1) or in the ingredient list in the following cases: when it appears in the product sales name or is usually associated with that name by the consumer; when it is emphasized on the labeling in words, pictures or graphics; when it is essential to characterize a foodstuff and to distinguish it from products with which it might be confused due to its name or appearance. However, the ingredient quantity does not have to be expressed in the following cases: when the net quantity (weight/volume) is shown on the label; when quantities are already required to be shown on the label under EU provisions; when ingredients are used in small quantities as flavoring; when variations in quantity are not essential to characterize the foodstuff or to tell the difference from similar foods.

Modified starches should indicate the vegetable origin when they may contain gluten.

2.4 If the product contains artificial sweeteners, added sugars and artificial sweeteners, aspartame, and polyols (in a proportion of more than 10 percent), labels must bear the following indications: “CON EDULCORANTE(S)”, CON AZUCAR(ES) Y EULCORANTE(S), “CONTIENE UNA FUENTE DE FENILAMINA”, and “UN CONSUMO EXCESIVO PUEDE TENER EFECTOS LAXANTES”, respectively.

3) Alcoholic beverages: For products with an alcoholic content exceeding 1.2 percent by volume, it must be shown and expressed as follows: "Alcohol" (or "Alc.") followed the figure with one decimal maximum and followed by "% vol."

4) Net weight/volume: net weight (Sp. PESO NETO) for solids or net volume (Sp. VOLUMEN NETO) for liquids, expressed under the metric system: liters (Sp. LITROS), centiliters (Sp. CENTILITROS), milliliters (Sp. MILILITROS), kilograms (Sp. KILOGRAMOS) and grams (Sp. GRAMOS). For those canned solid food products in water, in syrup, brined, in vinegar, and in fruit, legume or vegetable juices, both net weight (Sp. PESO NETO) and drained weight (Sp. PESO ESCURRIDO) must be shown.

5) Minimum product life: this statement is to be expressed by the legend "CONSUMIR PREFERENTEMENTE ANTES DEL ..." (To be consumed preferably before...) followed by the day and month, if product life is under three months, or followed by the month and year if product life is more than three months and less than eighteen months; or by the legend "CONSUMIR PREFERENTEMENTE ANTES DE FIN DE ..." (To be consumed preferably before the end of ...) followed by the year, if product life is over eighteen months.

- In the case of food products which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the "FECHA DE CADUCIDAD" (use by date). These words shall be accompanied by either the date itself or a reference to where the date is given on the labeling. The date shall consist of the day, the month and, eventually, the year.

Product life is not required for produce (except for sprouts), wines, beverages containing 10 percent or more by volume of alcohol as well as soft drinks, fruit juices and nectars for the institutional market, bakery and pastry products to be consumed within 24 hours of their manufacture, vinegar, cooking salt, solid sugar, confectionery products consisting almost solely of flavored and/or colored sugars, chewing gums and similar chewing products and individual portions of ice-cream.

6) Directions for product preservation, where applicable.

If the product is packed with any of the approved packing gases, label must include the following indication: “PREPARADO EN ATMOSFERA PROTECTORA”.

7) Nutritional labeling is compulsory where a nutritional claim appears on the label, in presentation or in advertising, with the exclusion of generic advertising. The only nutrition claims permitted shall be those relating to energy values and, to the following nutrients: protein, carbohydrate, fat, fiber, sodium, and prescribed vitamins, and to substances which belong to or which are components of a category of

the above nutrients.

8) Lot marking (i.e. a lot number preceded by the letter L) is required. It must be clearly legible and it must be indelible. Lot marking can be waived in those cases where the date of minimum durability or "use by" date appears on the label, provided that the date consists of at least the encoded indication of the day and the month in that order.

9) Other - Label must also include country of origin, (Sp. PRODUCTO IMPORTADO DE LOS EE.UU. or PRODUCTO IMPORTADO DE USA), as well as the importer's name and address (the same as registered in the Health Register for companies).

10) Non-packaged food : labeling of non-packaged food as well as foodstuffs packed at the point of sale, should indicate at least the product sales name (1). In addition, the indications set under the aforementioned art 2.4 where applicable, as well as the following: variety, grade and origin when required by food standards; for meats, cuts and grades; for fishery and aquiculture products, the commercial appearance; the ingredient quantity as explained above; the alcoholic degree where applicable.

11) Organic products: labeling should also indicate the ingredient list unless it is exempted.

12) Seafood: Fresh and frozen seafood products including aquiculture products must be labeled in both packaging and consumer packages including the following information: species commercial and scientific name; the catching zone according to FAO designation or the name of the country of origin in the case of fresh water or aquiculture products; the production method (ocean fish, Spanish "pesca extractiva" or fish "pescado", fresh water fish "pescado en agua dulce" or farmed "criado" or aquiculture "acuicultura" or shellfish "marisqueo"); whole ("entero"), fillets ("filetes"), other ("otros"); Frozen ("congelado"). Defrosted products must bear an indication of defrosted ("descongelado") and use by date ("fecha de caducidad").

13) Novel foods: Novel foods should also indicate the provisions laid down in Art. 8 of EU Regulation 258/97 on novel foods and novel foods ingredients. In addition, EU Regulation 1139/98 establishes that foodstuffs derived from genetically modified organisms (GMO) soybeans and corn when protein or DNA resulting from genetic modification is present should bear in the ingredient list the following words: "produced from genetically modified soya or corn" in parenthesis immediately after the name of the ingredient concerned. Alternatively, the words may appear in a prominent display footnote to the list of ingredients, related by means of an asterisk (*) to the ingredient concerned. When an ingredient is already listed as being produced from soya or corn the words 'produced from genetically modified' may be abbreviated to "genetically modified"; in footnotes, the asterisk should be directly attached to the word "soya" or "corn". In the case of foodstuffs without ingredients list, the words "produced from genetically modified soya/corn" should appear clearly on the labeling of the food. More recent regulations, including EU Regulations 49 and 50/2000 which were in force beginning on April 10, 2000, established that material derived from GMOs, either ingredients or food comprising of a single ingredient, are exempted from labeling when they are in a proportion of no higher than one percent. In addition, the ingredient list of foodstuffs having additives and flavorings derived from GMO products

should also be read with the words "produced from genetically modified.." New legislation on labeling and traceability of food and animal feed products containing or derived from GMOs is being passed (see section on Novel Food/Feeds, page 17)

14) Foodstuffs packed by retailers: labeling of these products for immediate sale at the retailing establishment should include the mandatory information set under art. 1, with the exception of the lot marking. The company identification, should be referred in any case to the packer. Labeling of plastic or other transparent bags containing fruits, vegetables, tubers or nuts should include the product sales name, variety, grade and origin when required by standards as well as the net weight and the company identification.

15) Mandatory information presentation: mandatory information in packed foodstuffs should be indicated in the container or in a label attached to the container. However, this information can be shown in the commercial documentation accompanying the packed foodstuffs as long as they are destined to end users but marketed in a previous stage to the sale to the end user. In addition, when they are destined to HRI establishments to be processed, fragmented or cut in those establishments. In any case, the indications including product sales name, product life and company identification should also be shown in the external package at the time of sale.

In addition, it is required that labeling information on product sales name, net quantity, date marking, and alcoholic degree when applicable, should be placed in the same field of vision.

Labeling information on non-packaged foodstuffs should be placed in labels or tags above or next to them. Labeling information on foodstuffs packed by retailers will be shown on packs or labels attached to them or in tags at the point of sale when there is a salesperson. In supermarkets, the product sales name of packaged produce and nuts in transparent bags can be placed in tags near the products.

ANNEX I: Ingredient categories for which specific ingredients should be named

Specific ingredient	Ingredient Category
Refined oils, other than olive oil	Aceite vegetal or Aceite animal followed by the term hidrogenado (hydrogentated) when applicable
Refined fats	Grasa vegetal or animal adding the term hidrogenado (hydrogentated) when applicable
Flour mixtures	Harina, followed by the grain species to whom flours belong to in decreasing order of weight
Starch(es), including modified	Almidon(es)
Fish, any kind,	Pescado
Cheese(s), any kind	Queso(s)

Spice(ies) and extracts, representing no more than 2 percent of the product weight	Especia (s) or Mezclas de especias
Aromatic plant(s) and its parts, representing no more than 2 percent of the product weight	Planta(s) Aromatica(s) or Mezclas de plantas aromaticas
Gums, utilized for making chewing gums bases	Goma base
Breadcrumbs	Pan rallado
Sucrose, any type	Azucar
Dextrose, anhydrous or monohydrated	Dextrosa
Glucose syrup and anhydrous glucose syrup	Jarabe de glucosa
Milk proteins, all (casein, caseinate, whey proteins) and its mixtures	Proteinas de leche
Cocoa butter, expeller or refined	Manteca de cacao
Comfits, not exceeding 10 percent of product weight	Frutas confitadas
Vegetable mixtures, representing no more than 2 percent of the product weight	Hortalizas
Wine, grape, any kind	Vino

ANNEX II: ADDITIVE GROUPS

<i>Coloring Agents</i>	Colorantes	<i>Preservatives</i>	Conservadores
<i>Antioxidants</i>	Antioxidantes	<i>Emulsifiers</i>	Emulgentes
<i>Thickeners</i>	Espesantes	<i>Gelling Agents</i>	Gelificantes
<i>Stabilizers</i>	Estabilizantes	<i>Flavoring Agents</i>	Potenciadores del Sabor
<i>Acidifying Agents</i>	Acidulantes	<i>Anticaking Agents</i>	Antiaglomerantes
<i>Acidity Correctors</i>	Correctores de la Acidez	<i>Artificial Sweeteners</i>	Edulcorantes Artificiales
<i>Modified Starches</i>	Almidones Modificados (1)	<i>Covering Agents</i>	Agentes de Recubrimiento
<i>Gasifying Agents</i>	Gasificantes	<i>Antifoaming Agents</i>	Antiespumantes
<i>Flour Treating Agents</i>	Agentes de Tratamiento de la Harina	<i>Melting Salts</i>	Sales Fundentes (2)
<i>Hardeners</i>	Endurecedores	<i>Moistening Agents</i>	Humedecedores
<i>Loading Agent</i>	Agente de Carga	<i>Propelling Gas</i>	Gas Propulsor

- (1) Specific name and number not required
- (2) Only in the case of melted cheeses or products with a melted cheese base

B. Requirements Specific to Nutritional Labeling (Royal Decree 930/92)

Article 1. Application and scope.

1. This Decree rules nutrition labeling for foodstuffs to be delivered as such to the ultimate consumer. It shall also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers. These requirements are in addition to those established by Royal Decree 2685/1976 and 1809/1991 (sanitary-technical regulation for the preparation, distribution and trade of foodstuffs for dietetic and/or other special food).

2. This Decree shall not apply to:

- a) Natural mineral waters or other waters intended for human consumption.
- b) Diet integrators/food supplements.

Article 2. Mandatory labeling requirements

Labeling on nutritional properties will be mandatory when label states that product is of nutritional value, excluding promotional campaigns on generic products. In other cases, labeling on nutritional properties is optional.

Article 3. Definitions

For the purpose of this Decree:

1. "Nutrition labeling" means any information appearing on labeling and relating to:

- (a) Energy value
- (b) The following nutrients:

Proteins

Carbohydrates

Fats

Fiber

Sodium

Vitamins and minerals listed in the Annex and present in significant amounts as defined in that Annex.

2. "Nutrition claims" means any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to:

- (a) The energy value it provides, at a reduced or increased rate, or does not provide.
- (b) The nutrients it contains, at a reduced or increased rate, or does not contain.

A reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation.

3. "Protein" means the protein content calculated using the formula:

$$\text{protein} = \text{total Kjeldahl nitrogen} \times 6.25.$$

4. "Carbohydrates" means any carbohydrate which is metabolized in man, and includes polyalcohols.

5. "Sugars" means all monosaccharides and disaccharides present in food, but excludes polyalcohols.

6. "Fat" means total lipids, and includes phospholipids.
7. "Saturates" means fatty acids without double bond.
8. "Mono-unsaturates" means fatty acids with one cis double bond.
9. "Polyunsaturates" means fatty acids with cis, cis-methylene interrupted double bonds.
10. "Fiber" means the material to be defined in accordance with the procedure laid down by the EC and measured by the method of analysis to be determined in accordance with that procedure.
11. "Average value" means the value which best represents the amount of the nutrient which a given food contains, and reflects allowances for seasonal variability, patterns of consumption and other factors which may cause the actual value to vary.

Article 4 - Admitted claims

The only nutrition claims permitted shall be those relating to energy, to the nutrients listed in paragraph 1.b), Article 3, and to substances which belong to or which are components of a category of those nutrients.

Article 5 - Labeling information options

1. Where nutrition labeling is provided, the information to be given shall consist of either group 1 or group 2 in the following order:

(A) Group 1

- (a) Energy value
- (b) The amounts of protein, carbohydrates and fat.

(B) Group 2

- (a) Energy value
- (b) The amounts of protein, carbohydrates, sugars, fat, saturates, fiber and sodium.

2. Where a nutrition claim is made for sugars, saturates, fiber or sodium, the information to be given shall consist of group 2.

3. Nutrition labeling may also include the amounts of one or more of the following:

Starch
Polyalcohols
Mono-unsaturates
Polyunsaturates
Cholesterol

Any of the minerals or vitamins listed in the Annex and present in significant amounts as defined in that Annex

4. The declaration of substances which belong to or are components of one of the categories of nutrients referred to in paragraphs 1 and 3 of this article 5 shall be compulsory where a nutrition claim is made.

In addition, where the amount of polyunsaturates and/or mono-unsaturates and/or the cholesterol rate is given, the amount of saturated shall also be given, the declaration of the latter not constituting - in this case - a nutrition claim within the meaning of paragraph 2 of this article.

Article 6 - The conversion factors to calculate energy value to be shown on label are as follows:

- Carbohydrates (except polyalcohols) 4 kcal/g = 17 KJ/g
- Polyalcohols 2,4 kcal/g = 10 KJ/g

- Protein	4 kcal/g = 17 KJ/g
- Fat	9 kcal/g = 37 KJ/g
- Alcohol (ethanol)	7 kcal/g = 29KJ/g
- Organic acid	3 kcal/g = 13KJ/g

Article 7 - Quantitative presentation of the information

1. The declaration of the energy value and of the proportion of nutrients or their components shall be numerical. The units to be used are the following:

Energy	KJ and kcal
Protein	Grams (g)
Carbohydrates	Grams (g)
Fat(except cholesterol)	Grams (g)
Fiber	Grams (g)
Sodium	Grams (g)
Cholesterol	Milligrams (mg)
Vitamins and minerals	The units specified in the Annex

2. Information shall be expressed per 100 g or per 100 ml. In addition, this information may be given per unit as quantified on the label or per portion, provided that the number of portions contained in the package is stated.

3. The amounts mentioned shall be those of the food as sold. Where appropriate, this information may relate to the foodstuff after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption.

4. Information on vitamins and minerals must also be expressed as a percentage of the recommended daily allowance (RDA) given in the Annex shown below and for the amounts specified in paragraph 2, Article 7.

The percentage of recommended daily allowance (RDA) for vitamins and minerals may also be given in graphical form.

5. Where sugars and/or polyalcohols and/or starch are declared, this declaration shall immediately follow the declaration of the carbohydrate content in the following manner:

*Carbohydrates/g, of which

- Sugars g
- Polyalcohols g
- Starch g

6. Where the amount and/or type of fatty acid and/or the cholesterol rate is declared, this declaration shall immediately follow the declaration of total fats in the following manner:

*Fats/g, of which:

- Saturates g
- Mono-unsaturates g
- Polyunsaturates g
- Cholesterol mg

7. The declared values shall, according to the individual case, be average values based on:

- (a) manufacturer's analysis of the food
- (b) a calculation from the known or actual average values of the ingredients used.
- (c) a calculation from generally established and accepted data.

Article 8 - Label structure information

1. The information covered by this Decree must be presented together in one place in tabular form, with the numbers aligned if space permits. Where space does not permit, the information shall be presented in linear form.

It shall be printed in legible and indelible characters in a conspicuous place.

2. The mandatory labeling declaration of nutrition value of foodstuffs marketed in Spain will be indicated in the way established by Article 20 of the General Labeling Requirements, Presentation and Publicity of Food Products approved by Royal Decree 212/1992, dated March 6.

3. In the case of non-prepackaged foodstuffs put up for sale to the ultimate consumer and to restaurants, hospitals, canteens and other similar mass caterers, or foodstuffs packed at the point of sale at the request of the purchaser, there must be a sign next to the products with all the information that should be included in the label of a prepackaged product, in accordance with Article 5, expressed and structured according to Articles 7 and 8.

4. The products prepackaged by the owners of the retail trade with a view to immediate sale will be accompanied by a label, in accordance with the requirements in paragraph 3 of this article.

Annex

Vitamins and minerals which may be declared and their recommended daily allowance (RDA)

Vitamin A	ug:	800	Vitamin B12	ug:	1
Vitamin D	ug:	5	Biotin	mg:	0.15
Vitamin E	mg:	10	Pantothenic acid	mg:	6
Vitamin C	mg:	60	Calcium	mg:	800
Vitamin B1	mg:	1.4	Phosphorus	mg:	800
Vitamin B2	mg:	1.6	Iron	mg:	14
Vitamin B3	mg:	18	Magnesium	mg:	300
Vitamin B6	mg:	2	Zinc	mg:	15
Vitamin B9	ug:	200	Iodine	ug:	150

As a rule, 15 percent of the recommended allowance specified in this Annex supplied by 100 g or 100 ml or per package if the package contains only a single portion should be taken into consideration in deciding what constitutes a significant amount.

C. Labeling Restrictions (Royal Decree 1907/96)

Advertising and Promotion of food products containing preventive, therapeutic or curative properties are banned.

SECTION III. PACKAGING AND CONTAINER REGULATIONS

Container Size Requirements: Royal Decree 1472/89 and its amendment Royal Decree 151/94 establish Container Size Standards for a number of packaged food products. These two laws are transpositions of EU Directives 88/316 and 89/676.

Wood Packaging Material: Wood packing material (NMWP) made of coniferous species (pine, spruce, fir, but not western red cedar) originating in several countries including the United States is required to be treated (either heat, or pressure treated or fumigated with an approved chemical) and marked to prevent the introduction of pinewood nematodes. The heat treatment must be officially approved and must utilize an official seal. More information can be found on the APHIS web site www.aphis.usda.gov/ppq/swp/eunmwp.html

Consumer Packaging: Packages destined to end consumers must carry the “eco-packaging” logo. However, if the product is processed and repacked in other packages, they do not have to carry such a logo since they are not destined to end consumers.

SECTION IV. FOOD ADDITIVE REGULATIONS

EU additive lists have already been transposed into the Spanish legislation, as follows:

- 1) Spain’s Royal Decree 2001/95, Regulation 1387 on Colors (*E.U. Directive 36/94, E.U. Official Journal L 237, 09/10/94*)
- 2) Spain’s Decree 2001/95, Regulation 767 on Artificial Sweeteners (*E.U. Directive 35/94, E.U. Official Journal L 237, 09/10/94*).
- 3) Spain’s Royal Decree 142/02 on Food Additives Other Than Colors and Sweeteners, (*E.U. Official Journal L 61, 03/18/95 and L 55, 02/24/01*)

As indicated above, flavors are regulated by the following legislation:

- 4) Spain’s Royal Decree 1477/90 on Flavors

Those EU additive lists and its amendments, as any other EU law can be searched and obtained through the Internet, as follows:

- Free of charge:

Search engine: <http://europa.eu.int/eur-lex/en/search.html>

The Official Journal: published daily, full texts are available for 45 days following publication

<http://europa.eu.int/eur-lex/en/oj/index.html>

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Phone: 34-91 538-2111
Fax: 34-91 538-2121
E-mail: clientes@com.boe.es

SECTION V. PESTICIDE AND OTHER CONTAMINANTS

Pesticides Residues: Annex II of Royal Decree 280/1994 lists pesticide residue on vegetable products, establishing maximum allowances by compound and groups of vegetable species. It has been amended many times to include new pesticides. The Spanish Ministry of Agriculture is responsible for monitoring and sampling imported vegetable products. U.S. exporters of fruit and vegetables can check compliance with the residue legislation through a data base which is available on the Spanish Agriculture Ministry's website, at the following address:

<http://www.mapya.es/productosfitos/ProducFito/consulta.htm>

Residues on Animal foodstuffs: The Ministry of Health is responsible for monitoring and sampling drug and pesticide residues on imported animal foodstuffs. The primary focus is on growth promoters and antibiotics. Poultry products are not sampled for residues. Meat offal are randomly sampled for residues, depending on the availability of the appropriate tissue.

Pesticide making, marketing and utilization in Spain are governed by Royal Decree 3349/83. A special commission composed of representatives from the central Ministries of Health and Agriculture is responsible for the registration and approval of new drugs, as well as pesticides. Lists of approved drugs and pesticides are maintained. There is currently in force a harmonized system for authorization, utilization and marketing of pesticides as established under EU Directive 414/91. Applications for authorization must be submitted by the responsible person of the first marketing of the product in Spain or its representative to the Direction General for Plant Health, Ministry of Agriculture.

Other contaminants: EU Commission Regulation 194/97 set maximum levels for certain contaminants in foodstuffs, including nitrogen in fresh lettuce as well as in fresh and processed spinach.

This regulation has been amended by EU Commission Regulation 1528/98 which set maximum levels of aflatoxins allowed in peanuts, tree nuts and dried fruit, cereals and milk. In addition, EU Commission Directive 53/98 establishes sampling and analysis methods for aflatoxins in foodstuffs. More recently, EU Council Regulation 2375/01 set dioxin limits for meat and products, liver, fish and products, milk and products, eggs and products, vegetable oils, animal fats and fish oil. The sampling and testing methods for dioxins are set by Spanish Royal Decree 604/2003.

In addition, Commission Regulation 472/02 set okratoxin A limits for grains and products, dried vine fruit such as raisins, currants and sultanas and certain other species. The sampling and testing methods for Okratoxin A are defined by Commission Directive 2002/26.

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

Registration: Imported foodstuffs are not subject to registration in the Food Register (Registro). Only drinking water and the diet and/or special food products listed below need registration. And so need "energy drinks for sportmen" but not other energy drinks with tuarine,caffeine and vitamins.

- Baby foods
- Low calorie products-food products to control weight
- Diet food of special medical uses
- Low sodium foods including low/no sodium salt
- Non-gluten foods
- Special foods for sportsmen
- Foods for diabetics
- Foods products enriched with vitamins, minerals or gin-seng
- Other food products of special uses

To register diet/special food products, drinking water and "energy drinks for sportsmen" the importer must submit a form called "Puesta en Mercado de Dieteticos" accompanied by a copy of the label to the Registro. The register (Registro Sanitario de Alimentos) is located at the Central Government's Ministry of Health and Consumption at the address provided in Section IX.

All wine importers must be registered at a Spanish Customs special register called "Registro Especial de Gestion Aduanera". In Madrid, this register is located in the Customs headquarters at the following address: Direccion General de Aduanas, Ministerio de Economia y Hacienda, Guzman El Bueno, 132; 28003 Madrid.

Laboratory testing:

Food products imported into Spain are not subject to approval prior entry, label and ingredients clearance or laboratory testing other than random sampling and testing for residues.

Certification Requirements:

– For live animals, semen, embryos, hatching, eggs, petfood, pig bristles, animal casings, apiculture products, dried bones & products, raw materials for pharmaceuticals, serum, dogchews: need a certificate issued by the Animal and Plant Health Inspection Service (APHIS-USDA). For more information, exporters should contact the following office:

Dr. Najam Faizi
Senior Staff Veterinarian
ANIMAL AND PLANT HEALTH
INSPECTION SERVICE
Veterinary Services
Import/Export Animals Staff
Unit 39
4700 River Road
Riverdale, MD 20737-1228
Tel: (301) 734-8383
Fax: (301) 734-6402

- For fresh fruit, vegetables and nuts: generally need a phytosanitary certificate issued by the Animal and Plant Health Inspection Service (APHIS-USDA). For more information, please contact:

APHIS/PPQ

Export Certification Unit Port Operations Staff
4700 River Road Unit 140
Riverdale MD 20737-1236
Phone: (301)-734-8453
Fax: (301)-734-5786

- For canned fruit and vegetables, sauces, and other processed foodstuffs not containing meat, fish, egg or dairy products: official certificate from U.S. governing authority indicating that the producing plant is authorized to produce these products for local consumption as well as for exports.

- For processed food products containing meat, fish, egg or dairy products: need special health certificates provided by U.S. authorities as follows:

The Food Safety Inspection Service (FSIS-USDA) for meats & meat products. For more information, please contact the following office:

Dr. Karen Morris
Food Safety and Inspection Service
Export-Import Program Analysis
Technical Service Center
106 South 15th Street
Omaha, NE 68102
Tel: (402) 221-7400
Fax: (402) 221-7438

The Food&Drug Administration (FDA) in conjunction with the U.S. Fish and Wildlife Inspection for fish products and seafood. For more information, please contact the FDA's Office of Seafood (phone number 202 418-3150)

The Agricultural Marketing Service (AMS-USDA) for dairy and egg products. For more information, please contact the following office:

Mr. Richard McKee
Deputy Administrator, Dairy Programs
Agricultural Marketing Service
U.S. Department of Agriculture
14th & Independence Ave., S.W., Rm 2968-S
Washington, D.C. 20090-5751
Tel: (202) 720-5751
Fax: (202) 690-3410

- For wood products: APHIS certification is required for several species, including oak, chestnut, sycamore, poplar and maples (acer saccharum in particular), oak staves and barrels, cases, boxes, crates, drums and similar packings of wood, and pallets. Oak logs with bark need special treatment and certification and can only enter Spain through the following three ports: Valencia, Bilbao and Vigo. A "Heat Treatment Certificate" is required for softwoods, and a "Certificate of Debarking and Grub Hole Control" is required for Western Red Cedar wood. These two certificates are issued by APHIS-validated agencies.
- For organic products: certification is required from approved certifying agencies (to obtain a list, please refer to Organic Foods in section VII).

Meat & Meat Products, Milk & Milk Products:

Animal products, including meat products, red meat, wild game meat, farmed game meat, milk & milk products, animal casings, bovine embryos, bovine semen, porcine semen, equine semen and seafood, can be only be imported in Spain from U.S. plants approved by the E.U. This system, however, will be in place until the U.S.-EU veterinary equivalence agreement will become effective. This will permit the U.S. health authority to approve plants to export to the E.U.

Beef from cattle that has been raised with growth promotants (hormones) can not be imported into the EU. In addition, meat and bone meal are banned. Animal fats such as tallow and yellow grease are now subject to stringent requirements for use or imports into the EU.

SECTION VII. OTHER SPECIFIC STANDARDS

Novel Foods/Feeds : In May 1997, the EU's Novel Foods Regulation went into force which called for labeling of products derived from genetically modified organisms (GMOs).

The EU Parliament has just given its approval of new legislation on the labeling and traceability of food and animal feed products containing or derived from GMOs. Process-based labeling will be required irrespective of whether the derived product contains detectable DNA or protein of GM origin. Thus, the label will require "genetically modified" or "derived from GM" (ingredient name).

The EU Parliament also approved a 0.9 percent tolerance for adventitious presence of GM materials approved in the EU and a 0.5 percent tolerance for those GM materials which have been scientifically approved by EU experts but without final clearance. The latter threshold, however, will only apply for three years, leading to a total EU ban on foodstuffs or feed products containing non-approved GM materials. In addition, even refined oils with no GM materials will have to be labeled. This legislation will likely become effective in January 2004.

Strict procedures will also ensure the 'traceability' of GM products through the production chain. Information on GM content of products must be transmitted from one operator to the next, and information must be kept on file for five years. This legislation was a key condition for the lifting of the

existing moratorium for the approval of new GM products in the EU. Since seven member states currently support the lifting, it is likely that the EU will resume approvals soon.

Organic Foods: Organic products (SP. PRODUCTOS ECOLÓGICOS) are clearly identified through specific labeling rules intended to provide the consumer with a guarantee of origin, preparation, processing and packaging. EC Regulation 2092/91 of June 24, 1991 lays down the main principles for organic production and the rules that must be followed for the processing, sale and importation of organic products in all EU countries, including Spain. EU regulation 1804/99 covers organic livestock products. Organic products exported from the U.S. to Spain must be certified as such.

USDA/American Marketing Service (AMS) is responsible for creating a list of accredited U.S. certification agencies. Such a list can be obtained from the Agricultural Affairs Office of the U.S. Mission to the European Union at the following website: <http://www.useu.be/agri/organic.html>

Product Samples and Mail Order Shipments:

The pertinent health certificates and invoices are required for samples and mail order shipments. Invoices for sample shipments must carry the statement “Muestras Sin Valor Comercial” (“Samples Without Commercial Value”). Sample shipments can be made under a “Temporary Importation Under Bond” basis. Bonds are reimbursed when product samples are re-exported to the U.S. Consumable items and give-away samples, however, are subject to regular import tariffs.

SECTION VIII. COPYRIGHT/TRADEMARK LAWS

Spain is a signatory to the Paris Convention for the Protection of Industrial Property. Both the Trademark Law of November 1988 (Law 32) and the Intellectual Property Law 1750/87 address protection for brand names and trademarks. Spain is also a party to the Madrid Agreement on Trademarks. These laws follow E.U. standards. The Intellectual Property Law of November 1987 offers copyright protection.

Trademarks: The Industrial Property Registry provides protection of trademarks for a 10-year period from the date of application. Trademarks must be registered for protection and may be renewed. Protection is not granted for generic names, geographic names, those that violate Spanish customs, or other inappropriate trademarks.

Copyrights: The law extends copyright protection to all literary, artistic, or scientific creations, including computer software. Spain and the United States are members of the Universal Copyright Convention. For protection, U.S. authors must register with this organization.

The Office for Harmonization in the Internal Market (OHIM) for the registration of community trademarks in the European Union started its operations in 1996 and has its headquarters in Alicante (Spain):

Oficina de Armonización del Mercado Interior
-Office for Harmonization in the Internal Market-

Avenida Aguilera, 20
03080 Alicante
Tel: (34 96) 513-9100
Fax: (34 96) 513-9173

SECTION IX. IMPORT PROCEDURE

Importers may be any individual or company with an address in Spain and having a fiscal I.D. from the Ministry of Finance (Ministerio de Economia y Hacienda). They should also be registered at the Public Health Unit of the Autonomous Region's Government where they are located.

In the case of the Madrid Region, the Register for importers is located at the following address: La Aduana, 29 - planta baja; 28013 Madrid; Tel: (91) 586-7166; Fax: 91 586-7170

Importers, however, may also be any EU firm though not having a domicile in Spain. In this case, they can only be those registered with the Central Government's Ministry of Health at the following address:

Registro Sanitario de Alimentos
Direccion General de la Salud Publica
Subdireccion General de Higiene de los Alimentos
Ministerio de Sanidad y Consumo
Paseo de Prado, 18-20
28071 Madrid
Phone: (34) 91 596-1966 and 91 596-1950
Fax: (34) 91 596-4487

This is also the place for registering the food products mentioned in Section VI.

Importers must have a sanitary registration number which. Their names and addresses, exactly as they are registered, must appear on the label.

The following documentation is required for customs clearance of food products:

- 1) Bill of lading
- 2) Certificate of Origin
- 3) An original Commercial Invoice with a copy
- 4) An import declaration
- 5) Health Certificates (as described under the section for Certification)

A customs agent or broker is normally involved in clearing products at customs. Import declarations are made at the State Secretariat of Commerce or its branch delegations in major port cities throughout the country. Declarations must use the exact terminology of the tariff classification under which the goods are being imported. A three-month grace period is allowed for U.S.-origin goods arriving without

proper documentation, subject to a written guarantee by the customs agent.

The Ministry of Agriculture has offices at Customs for the sanitary and phytosanitary inspection of live animals, agricultural commodities, fresh produce, planting seed and forest products as well as the Ministry of Health for the veterinary/sanitary inspection of meat, fish and processed food products.

APPENDIX I- GOVERNMENT REGULATORY AGENCY CONTACTS

MINISTRY OF PUBLIC HEALTH

Imported Foodstuffs, Infections and Compound Residues, Health Certification

Subdirección General de Sanidad Exterior

Ministerio de Sanidad y Consumo

Paseo del Prado, 18 y 20

28014 Madrid

Phone: (34-91) 596-2040

Fax: (34-91) 596-2047

Food Hygiene, Labeling, Ingredients, Additives

Subdirección General de Higiene de los Alimentos

Ministerio de Sanidad y Consumo

Paseo del Prado, 18

28014 Madrid

Phone: (34-91) 596-1964

Fax: (34-91) 596-4409

MINISTRY OF AGRICULTURE, FISHERIES AND FOOD

Plant Health Unit, inspection and certification

Subdirección General de Sanidad Vegetal

Ministerio de Agricultura, Pesca y Alimentación

Avda. Ciudad de Barcelona, 6

28007 Madrid

Phone: (34-91) 347-8258

Fax: (34-91) 347-8263

Animal Health Unit, inspection and certification

Subdirección General de Sanidad Animal

Ministerio de Agricultura, Pesca y Alimentación

Velázquez, 147

28002 Madrid

Phone: (34-91) 347-8295

Fax: (34-91) 347-8299

Planting seeds and Nursery Products, governing several seed trade aspects such as import requirements, seed registration and certification, and the commercial seed catalog.

Registro de Variedades Vegetales
Ctra. de la Coruña, Km. 7,5
28040 Madrid
Phone: (34-91) 347-6908
Fax: (34-91) 347-4168

Pesticides, Registration and MRLS establishment:
Subdirección General de Medios de Producción Agrícola
Ministerio de Agricultura, Pesca y Alimentación
Avda. Ciudad de Barcelona, 118
2007 Madrid
Phone: (34-91) 347-8291
Fax: (34-91) 347-8316

APPENDIX II- OTHER IMPORT SPECIALIST CONTACTS

Office of Agricultural Affairs, Madrid <http://www.embusa.es>
e-mail: AgMadrid@fas.usda.gov
Lloyd Fleck, Agricultural Counselor **e-mail: FleckL@fas.usda.gov**
Diego Pazos, Agricultural Specialist **e-mail: PazosD@fas.usda.gov**
Diego Perez de Ascanio, Agricultural Specialist **e-mail: PerezD@fas.usda.gov**
Magdalena Escudero, Marketing Specialist **e-mail: EscuderoM@fas.usda.gov**
Pilar Munoz, Marketing Assistant **e-mail: MunozPilar@fas.usda.gov**

Foreign Commercial Service, Barcelona: <http://www.embusa.es>
Pesticide Authorization and Registration:
Monserrat Canela **e-mail: mcanela@doc.gov**